NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Nintedanib for treating idiopathic pulmonary fibrosis

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of nintedanib within its licensed indication for treating idiopathic pulmonary fibrosis.

Background

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive lung disease in which scarring (fibrosis) occurs. The cause of IPF is unknown although it is thought to be related to an abnormal immune response to an unknown cause. It is a difficult disease to diagnose and requires a multidisciplinary team. Most people with IPF experience symptoms of breathlessness, which may initially be only on exertion. Cough, with or without sputum, is a common symptom. Over time, these symptoms are associated with a decline in lung function, reduced quality of life and death.

The median survival for people with IPF in the UK is approximately 3 years from the time of diagnosis. However, about 20% of people with IPF survive for more than 5 years. The rate of disease progression can vary greatly. Prognosis is difficult to estimate at the time of diagnosis and may only become apparent after a period of careful follow-up.

The incidence of IPF is approximately 8 to 9 per 100,000 person-years, which equates to more than 5000 new diagnoses each year in the UK. The incidence is higher in men than women, and increases with age (median age of presentation is 70 years). IPF co-exists with chronic obstructive pulmonary disease in around 8-15% of people.

The aim of treatment is to manage the symptoms and slow progression. NICE clinical guideline 163 on the diagnosis and management of suspected idiopathic pulmonary fibrosis recommends that best supportive care (including symptom relief, management of co-morbidities, withdrawal of therapies suspected to be ineffective or causing harm and end of life care) should be offered to people from diagnosis and be tailored according to disease severity, rate of progression and the person's preference. If pharmacological treatment is considered appropriate, the guideline recommends use of pirfenidone if a person's forced vital capacity (FVC) is between 50% and 80% of their expected value in line with recommendations in NICE technology appraisal guidance 282. Treatment with pirfenidone should be discontinued if there is evidence of disease progression (a decline in per cent predicted FVC of 10% or more within any 12 month period). Lung transplantation is an option if there are no contraindications.

The technology

Nintedanib (Ofev, Boehringer Ingelheim) targets 3 growth factor receptors involved in pulmonary fibrosis. The mechanism of nintedanib is not fully understood but it is thought that by blocking the signalling pathways involved in fibrotic processes, nintedanib may reduce disease progression by slowing the decline of lung function. It is administered orally.

Nintedanib has a UK marketing authorisation for treating idiopathic pulmonary fibrosis in adults.

Intervention(s)	Nintedanib
Population(s)	Adults with idiopathic pulmonary fibrosis
Comparators	• Pirfenidone (where appropriate) • Best supportive care
Outcomes	The outcome measures to be considered include: • pulmonary function parameters • physical function • exacerbation rate • progression-free survival • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any patient access schemes for the intervention or comparator technologies should be taken into account.

Other considerations	Guidance will only be issued in accordance with the marketing authorisation or CE marking. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: Technology Appraisal No. 282, April 2013, 'Pirfenidone for treating idiopathic pulmonary fibrosis'. Under review, anticipated date of publication TBC. Related Guidelines: Clinical Guideline No.163, July 2013, 'Idiopathic pulmonary fibrosis: The diagnosis and management of suspected idiopathic pulmonary fibrosis'. Review Proposal Date June 2015. Related Quality Standards: Quality Standard No. 79, January 2015, 'Idiopathic pulmonary fibrosis'. http://www.nice.org.uk/guidance/qs79 Related NICE Pathways: NICE pathway: Idiopathic pulmonary fibrosis, Pathway created June 2013. http://pathways.nice.org.uk/pathways/idiopathic-pulmonary-fibrosis
Related National Policy	National Service Frameworks: Older People Department of Health, November 2013, 'NHS Outcomes Framework 2014-2015'.